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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/905,235      | 07/13/2001  | Jeffrey A. Robl      | LA 24B ContI        | 3904             |

23914 7590 09/24/2003

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EXAMINER

MOHAMED, ABDEL A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/905,235             | ROBL ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Abdel A. Mohamed       | 1653                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### **RESTRICTION REQUIREMENT**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-15, drawn to a method for treating atherosclerosis comprising administering an aP2 inhibitor, classified in class 548, subclass 215+, for example.
  - II. Claims 16-20, drawn to a pharmaceutical combination comprising an aP2 inhibitor and another type antiatherosclerotic agent, classified in class 548, subclass 215+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination and each active component has use of its own.

Furthermore, the subcombination has separate utility such as a cholesterol-lowering agent.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classification, restriction for examination purposes as indicated is proper. Moreover, the consideration of patentability is not the same for both inventions AND the search is not coextensive. It would be undue burden on the examiner to examine both inventions in one application.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Election of Species Requirement***

5. Claims 1-20 are generic to a plurality of disclosed patentably distinct species comprising:

An oxazole or analogues ring, a pyrimidine derivative or a pyridazinone derivative as follows (set forth in claim 14):

Species of Groups (I): A and B (pages 43-44),

Species of Group (II): (pages 44-45),

Species of Group (III): (page 45),

Species of Group (IV): (page 45),

Species of Group (V): (page 46),

Species of Group (VI): (pages 46-47),

Species of Group (VII): VIIA and VIIB (pages 47-48),

Species of Group (VIII): (page 48),

Species of Group (IX): (pages 48-49),

Species of Group (X): XA, XB, XC and XD (pages 49-50),

Species of Group (XI): (page 50),

Species of Group (XII): (pages 50-51),

Species of Group (XIII): (page 51),

Species of Group (XIV): XIVA, XIVB, XIVC, XIVD, and XIVE (pages 51-52),

Species of Group (XV): (pages 53-56),

Species of Group (XVI): (page 56).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., a single compound), and to list all claims readable thereon including those subsequently added, even though this requirement is traversed. Further, Applicant should include a chemical structure of the elected species/compound if it is not disclosed in the specification.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to Steven Davis on 9/15/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention (I or II) and an election of the species, as set forth above, together with the election of **an ultimate** specie, including the chemical structure for the same, to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is further required to clearly indicate the claims already of record and reading on the elected species or draw new claim(s) to the elected species.

In the event Applicant elects Group II invention, Applicant is further required to elect specie for "another type antiatherosclerotic agent".

**Ultimate specie** of a compound is a compound wherein all the variable parameters in its chemical structure are accounted for.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **CONCLUSION AND FUTURE CORRESPONDANCE**

9. Claims 1-20 are subject to restriction and/or species election requirement


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 A.M. to 5:00 P.M. The examiner can also be reached on alternated Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196

 Mohamed/AAM

September 15, 2003



CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600